REMARKS/ARGUMENTS

Status of the Claims

After entry of this amendment, claims 1, 8-15, 22-24, and 28 are pending. Claims 2-7, 16-21 and 25-27 have been canceled without prejudice to future prosecution. New claim 28 has been added.

Claims 1, 8-15, 22-24 have been amended. Specifically, claims 1, 8-15, 22-23 have been amended to recite "isolated" antibody. Support for this amendment is found throughout the specification and claims as filed (*see*, e.g., page 14, lines 9-23). Claim 1 has been further amended to recite CDRs comprising SEQ ID NOS; 3-6 and claim 3 has been further amended to recite VH and VL domains comprising SEQ ID NOS: 1 and 2, respectively. Support for these amendments is found throughout the specification and claims as filed (*see*, e.g., page 17, lines 9-19). Claim 24 has been amended to address a grammatical issue. New claim 28 is directed to pharmaceutical compositions further comprising Factor IX, Factor IXaα, FactorIXaβ, and combinations thereof. Support for this amendment is found throughout the specification and claims as filed (*see*, e.g., claim 24). Thus, none of the amendments add new matter.

Rejection of the Claims under 35 U.S.C. § 101

The claims have been rejected under 35 U.S.C. § 101 as allegedly directed to non-statutory subject matter. In making this rejection, the Examiner has indicated that the recitation "isolated antibodies" would obviate the rejection. In accordance with the Examiner's suggestions, the claims have been amended to recite "isolated antibody." Accordingly, Applicants respectfully request that the rejection under 35 U.S.C. § 101 be withdrawn.

Rejection of the Claims under 35 U.S.C. § 112, first paragraph

The claims have been rejected 35 U.S.C., § 112, first paragraph as allegedly lacking enablement and written description. Applicants respectfully traverse each of these rejections below.

1. Enablement

Claims 1-7, 9-15, and 22-24 have been rejected under 35 U.S.C. § 112, first paragraph as allegedly lacking enablement for the claimed compositions. In making this rejection, the Examiner acknowledges that the specification enables antibodies that comprise SEQ ID NOS: 6-8 in CDR's 1-3 of the heavy chain and SEQ ID NOS: 3-5 in CDR's 1-3 of the light chain and for antibodies that comprise SEQ ID NOS:1 and 2 as the V_H and V_L domains, resepctively. Applicants have amended the claims in accordance with the Examiner's suggestion to recite that the claimed antibodies comprise a V_H domain having a CDR1 comprising the sequence set forth in SEQ ID NO:6, a CDR2 comprising the sequence set forth in SEQ ID NO:7, and a CDR3 comprising the sequence set forth in SEQ ID NO:8; and a V_L domain having a CDR1 comprising the sequence set forth in SEQ ID NO:3, a CDR2 comprising the sequence set forth in SEQ ID NO:4, and a CDR3 comprising the sequence set forth in SEQ ID NO:5.

In view of the foregoing remarks, Applicants assert that the present claims are fully enabled by the specification as originally filed. Accordingly, Applicants respectfully request withdrawal of the rejection under 35 U.S.C. § 112, first paragraph.

2. Written Description

Claims 1-7, 9-15, and 22-24 have been rejected under 35 U.S.C. § 112, first paragraph as allegedly lacking written description for the claimed antibodies. Applicants have amended the claims to recite that the claimed antibodies comprise a V_H domain having a CDR1 comprising the sequence set forth in SEQ ID NO:6, a CDR2 comprising the sequence set forth in SEQ ID NO:7, and a CDR3 comprising the sequence set forth in SEQ ID NO:8; and a V_L domain having a CDR1 comprising the sequence set forth in SEQ ID NO:3, a CDR2 comprising the sequence set forth in SEQ ID NO:4, and a CDR3 comprising the sequence set forth in SEQ ID NO:5." To the extent that the rejection applies to the currently pending claims, Applicants respectfully traverse.

The written description requirement is satisfied when the specification describes the claimed invention in sufficient detail that one of skill in the art can reasonably conclude that

the inventor had possession of the claimed invention (*see, e.g.*, MPEP § 2163(I), citing *Vas-Cath, Inc. v. Mahurkar*, 935 F.2d 1555, 19 USPQ2d 1111 (Fed. Cir. 1991). Possession can be shown by disclosure of relevant identifying characteristics of a genus including, *e.g.*, functional characteristics coupled with a correlation between structure and function (*see*, *e.g.*, MPEP § 2163(II)(A)(3)(a)(ii)) or by describing an actual reduction to practice of the claimed invention (*see, e.g.*, MPEP § 2163(II)(A)(3)(a), citing *Pfaff v. Wells Elecs., Inc.*, 525U.S. 55 48 USPQ2d 1641 (1998).

The claims are directed to isolated antibodies that can bind Factor IX/Factor IXa and increase the procoagulation activity of Factor IXa. As amended the claims also recite that the antibodies comprise the following structural features: a V_H domain having a CDR1 comprising the sequence set forth in SEQ ID NO:6, a CDR2 comprising the sequence set forth in SEQ ID NO:7, and a CDR3 comprising the sequence set forth in SEQ ID NO:8; and a V_L domain having a CDR1 comprising the sequence set forth in SEQ ID NO:3, a CDR2 comprising the sequence set forth in SEQ ID NO:4, and a CDR3 comprising the sequence set forth in SEQ ID NO:5.

Applicants respectfully assert that the disclosure of the specification is sufficient to demonstrate that antibodies with the recited structural features also possess the recited functional characteristics of binding Factor IX/Factor IXa and increasing Factor IXa procoagulation activity. For example, the specification provides a description of Factor IX/Factor IXa-binding antibodies comprising the recited V_H and V_L domains and sets forth the sequences for the V_H and V_L domains, including the sequences for each of the CDR sequences of the antibodies (*see, e.g.*, page 17, lines 9-19 and Figures 6, 7, and 8). As is well known in the art and as set forth in the specification, the CDR's are responsible for antibody binding to an antigenic epitope (*see, e.g.*, page 8, lines 3-9). Thus, a disclosure of CDR sequences is ample description for an antibody that binds Factor IX/Factor IXa.

Moreover, the specification sets forth several working examples that describe an actual reduction to practice of multiple antibodies with the recited structural and functional features. In particular, Example 4 describes experiments demonstrating that antibodies

comprising the recited CDR sequences bind Factor IX/Factor IXa and increase the procoagulation activity of Factor IXa (*see, e.g.*, page 35, line 27 to page 38, line 2); Example 6 describes *in vitro* experiments demonstrating that antibodies comprising the recited CDR sequences increase the procoagulation activity of Factor IXa (*see, e.g.*, page 38, line 22 to page 40, line 21); Example 7 describes *in vivo* experiments demonstrating that antibodies comprising the recited CDR sequences increase the procoagulation activity of Factor IXa (*see, e.g.*, page 40, line 22 to page 42, line 26); Example 8 describes experiments various antibodies comprising the recited CDR sequences bind Factor IX/Factor IXa and increase the procoagulation activity of Factor IXa (*see, e.g.*, page 42, line 29 to page 44, last line).

Thus, the specification provides a precise definition of an antibody molecule comprising of the recited structural features (*i.e.*, CDR sequences) and the correlation between the structural features and the functional properties of the antibodies (*i.e.*, binding Factor IX/Factor IXa and increasing Factor IXa procoagulation activity).

In view of the foregoing remarks, Applicants respectfully assert that written description has been satisfied for the pending claims by the teachings of the specification and request withdrawal of this aspect of the rejection under 35 U.S.C. § 112, first paragraph.

Objections to the Claims

1. Claim 1

Claim 1 is objected to for lacking the abbreviation "FIXa" following the recitation "Factor IXa." Claim 1 has been amended to replace the recitation "FIXa" with the recitation "Factor IXa.". Accordingly, Applicants respectfully request withdrawal of the objection.

2. Claim 24

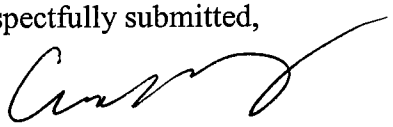
Claim 24 has been objected to for awkward language. Claim 24 has been amended to recite: Factor IX, Factor IXaα, FactorIXaβ, and combinations thereof. Support for this amendment is found in claim 24 as originally filed. Accordingly, Applicants respectfully request withdrawal of the objection.

CONCLUSION

In view of the foregoing, Applicants believe all claims now pending in this Application are in condition for allowance. The issuance of a formal Notice of Allowance at an early date is respectfully requested.

If the Examiner believes a telephone conference would expedite prosecution of this application, the Examiner is invited to telephone the undersigned at 925-472-5000.

Respectfully submitted,



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